With reference to FIG. **2**, softgel capsule, i.e. gel mass, production **200** is shown. Step **202** comprises mixing glycerin with water. The water used in step **202** may be purified by any suitable means, such as reverse osmosis, ozonation, filtration (e.g., through a carbon column) or the like. Mixing may be facilitated by an impellor, agitator, or other suitable means. Step **202** may be performed under an inert or relatively inert gas atmosphere, such as nitrogen gas N_2. Heating may be performed until the temperature reaches 80° C.±5° C.

Step **204** comprises the addition of gelatin to the glycerin water mixture. Mixing may be facilitated by an impellor, agitator, or other suitable means. Step **204** may be performed under an inert or relatively inert gas atmosphere, such as nitrogen gas N_2. A vacuum may be drawn in step **204** to de-aerate.

Step **206** comprises addition of a coloring agent such as a dye. A coloring agent may comprise products sold under the trademark OPATINT or other suitable agent. Step **206** may be performed under an inert or relatively inert gas atmosphere, such as nitrogen gas N_2. Step **208** comprises degasing. The resulting mixture from step **208** may comprise a gel capsule material suitable for use as a gel capsule in production of a softgel capsule.

With reference to FIG. **3**, softgel capsule assembly process **300** is shown. Step **302** comprises heating the fill material. The fill material may be heated to any suitable temperature. In various embodiments, the fill material is heated to 30° C.+/−3° C. Fill material maybe heated in a fill hopper. A fill hopper may comprise a device configured to hold a volume of the fill material and/or to dispense the fill material in controlled volumes.

Step **304** comprises filling a gel mass. A gel mass may be taken from the gel capsule material produced in step **208** of FIG. **2**. Filling may be performed by injecting, placing, or otherwise disposing the fill material within a volume defined by the gel capsule material. The filling may occur in an encapsulator. The spreader boxes may be a temperature of 55° C.+/−10° C. The wedge temperature may be 38° C.+/−3° C. The drum cooling temperature may be 4° C.+/−2° C. The encapsulator may be lubricated using MIGLYOL 812 or other suitable lubricant. Step **304** thus produces one or more softgel capsules. Filling may comprise producing a ribbon of thickness 0.85 mm±0.05 mm using spreader box knobs. The fill material may be injected into the gel to produce a fill weight having target weight±5% (i.e., 650±33 mg and 325±16.3 mg).

Step **306** comprises drying the softgel capsules. Drying may be performed in a tumble dryer, tray dryer, or combinations thereof. For example, drying may be performed in a tumble drying basket for between about 10 minutes and about 120 minutes. Drying may continue in a drying room for about 24 hours to about 72 hours. Step **308** may comprise inspection and/or polishing. Polishing may be performed with isopropyl alcohol. Step **310** may comprise packaging. Packaging may be accomplished through any suitable means. Packaging may comprise packing softgel capsules into a blister pack, bottle, box, pouch, or other acceptable packaging.

What is claimed is:

1. A pharmaceutical composition comprising:
solubilized estradiol;
suspended progesterone;
and a solubilizing agent;
wherein each of the estradiol and the suspended progesterone are present in the solubilizing agent and the estradiol and progesterone are uniformly dispersed;
wherein at least about 90% of the estradiol is solubilized in the solubilizing agent;
and wherein the solubilizing agent comprises predominately a saturated C6-C12 oil.

2. The pharmaceutical composition of claim **1**, further comprising partially solubilized progesterone, wherein the partially solubilized progesterone is solubilized in the solubilizing agent.

3. The pharmaceutical composition of claim **1**, wherein the formulation is formulated as a gelatin capsule.

4. The pharmaceutical composition of claim **1**, wherein said estradiol has a dosage strength of at least about 0.125 mg and wherein said progesterone has a dosage strength of at least about 25 mg.

5. The pharmaceutical composition of claim **1**, wherein the ratio of progesterone to estradiol is about 24:1, about 25:1, about 96:1, about 100:1, about 192:1, or about 200:1.

6. A pharmaceutical composition comprising:
solubilized estradiol;
suspended progesterone; and
a solubilizing agent, the solubilizing agent comprising predominately a saturated C6-C12 oil;
wherein the estradiol and the suspended progesterone are present in the solubilizing agent, the estradiol and progesterone are uniformly dispersed, and at least about 90% of the estradiol is solubilized in the solubilizing agent; and
wherein the estradiol does not precipitate for at least 14 days.

7. The pharmaceutical composition of claim **6**, further comprising partially solubilized progesterone, wherein the partially solubilized progesterone is solubilized in the solubilizing agent.

8. The pharmaceutical composition of claim **6**, wherein the composition is formulated as a gelatin capsule.

9. The pharmaceutical composition of claim **6**, wherein the estradiol has a dosage strength of at least about 0.125 mg and wherein the progesterone has a dosage strength of at least about 25 mg.

10. The pharmaceutical composition of claim **6**, wherein the ratio of progesterone to estradiol is about 24:1, about 25:1, about 96:1, about 100:1, about 192:1, or about 200:1.

11. A method of treating menopause symptoms in a woman with a uterus comprising:
administering an effective amount of a pharmaceutical composition, the pharmaceutical composition comprising solubilized estradiol, suspended progesterone, and a solubilizing agent;
wherein each of the estradiol and the suspended progesterone are present in the solubilizing agent, the estradiol and the suspended progesterone are uniformly dispersed and at least about 90% of the estradiol is solubilized in the solubilizing agent; and
wherein the solubilizing agent comprises predominately a saturated C6-C12 oil.

12. The method of claim **11**, further comprising partially solubilized progesterone, wherein the partially solubilized progesterone is solubilized in the solubilizing agent.

13. The method of claim **11**, wherein the composition is formulated in a gelatin capsule.

14. The method of claim **11**, wherein the estradiol has a dosage strength of at least about 0.125 mg and wherein the progesterone has a dosage strength of at least about 25 mg.

15. The method of claim **11**, wherein the ratio of progesterone to estradiol is about 24:1, about 25:1, about 96:1, about 100:1, about 192:1, or about 200:1.

* * * * *